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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,887

09/10/2008

Markus Eblenkamp

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ALLEMAN HALL MCCOY RUSSELL & TUTTLE LLP  
806 SW BROADWAY  
SUITE 600  
PORTLAND, OR 97205-3335

EXAMINER

CHAN, EMILY Y

ART UNIT

PAPER NUMBER

2858

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/588,887	EBLENKAMP ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	EMILY CHAN	2858	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4 and 7-15 is/are rejected.
- 7) ☒ Claim(s) 3 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/9/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Objections*

1. Claims 7 and 13 are objected to because of the following informalities: in the claim 7, line 5, the recitation, " the device an analysis unit " is unclear. The examiner suggests changing to " the device comprising an analysis unit ". In the claim 13, it is not specified where the " cultivation of cells, cell aggregates and/or tissue" are included. Appropriate correction is required.

### *Drawings*

Since the drawing sheets comprising Figs. 1-6 are missing in the file, applicant is required to furnish **a drawing comprising Figs 1-6** under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-2, 4-5 and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sammak et al (US Publication No. 2001/0041347) in view of Johnson et al (US Publication No. 2003/0048931).

With respect to the claims 1, 7, 10 and 13, Sammak et al('347) expressly disclose an apparatus and a method for characterizing **cells and cell aggregates** (see Figs. 1-6 and page 18, paragraph [0197], line 10, "**cell aggregate**") as claimed, comprising:

an **incubator** (see Fig. 4, No. 41, "**cell arrays**");  
an **analysis unit** (see Fig. 1, **PC 11** and claim 1, ) which includes means by which **morphological parameters** of cells and cell aggregates are detected, and which includes **means** by which the detected **morphological parameters are evaluated** for the purpose of the objective morphological characterization of the cells and cell aggregates (see claim 1, step f, " automatically **calculating** . . . cell-based **morphological features**").

Sammak et al ('347) fail to disclose a **database** and **comparator means** by which the detected parameters are compared with the reference parameters from the data base.

Johnson et al ('931) disclose quantitative geometrical analysis relating to characterization of tissue for the creation data and associated image (see page 1, paragraph [0002] ) comprising a **database** with the reference parameters stored (see Fig. 2 and page 1, paragraph [0009], "**database**"). More over, Sammak et al ('347) disclose **comparator means** (see page 3, paragraph [0098], line 14, "**data comparing**") by which the detected parameters are compared with the reference parameters from the data base (see page 3, paragraph [0095]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have adapted the database and comparator of Johnson et al ('931) into the method and apparatus of Sammak et al('347) and to have used the resulting combination to produce the apparatus for characterizing the cell, cell aggregates and/or tissue comprising the database and comparator means as claimed for the advantage of providing a database for easy retrieval and statistical analysis as disclosed by Johnson et al ('931) (see page 1, paragraph [0007], last line).

With respect to the claim 2, Sammak et al ('347) disclose that their **analysis unit** (see Fig. 1) comprises an **image-forming unit** ( **digital camera 7**) and an **image analysis unit** (**PC 11**).

With respect to the claims 4 and 11, Sammak et al ('347) disclose that their **analysis unit** includes means for the **statistical evaluation** of the detected morphological parameters (see page 10, paragraph [0122]).

With respect to the claim 8, Sammak et al('347) disclose that their apparatus (see Fig. 1) furthermore includes a **manipulator** (see Fig. 1, **automation controller 9**), a transporter (see Fig. 4, microplate chamber 42) for transporting one or more cell culture vessels between the incubator (41) (see page 6, paragraph [0078], the **manipulator** and the **analysis unit** as well as a **control unit** for operating the apparatus(see Fig. 1, No. 9,10,11).

With respect to the claim 9, Sammak et al ('347) disclose that their control unit is configured such that the apparatus is operated **automatically** (see page 8, paragraph, [0098] "**automatically moves**").

With respect to the claim 12, Johnson et al ('931) disclose that their **statistical values** are compared with values from a reference database (see page 3, paragraph [0095], last four lines “ **histograms of data arrays can be produced**” and see page 3, paragraph [0098], line 14, “ **data comparing**”).

With respect to the claim 14, Sammak et al('347) disclose that their **cell cultivation** (see Abstract, “**cell spreading**”) is performed in dependence on the evaluated parameters (see Fig. 4).

With respect to the claim 15, Sammak et al ('347) disclose that their detection and evaluation of the **morphological parameters** as well as the cultivation of cells are effected **automatically** (see claim 1, f) “ **automatically** calculating . . . cell-based **morphological features**”).

### ***Allowable Subject Matter***

3. Claims 3 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The claims 3 and 6 are objected to because the examiner does not find the prior art on the record before the filing date of 11/2/2004 disclose or fairly suggests the analysis unit configured such that a degree of confluence, a cell morphology as a measure for the quality of the cell culture, a proliferation behavior, a presence of microorganisms and/or cell differentiation can be

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detected and evaluated recited in the claim 3 and the analysis unit which includes means by which adjacent pixels of a detected image with similar brightness values are combined to one image object recited in the claim 6.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wilkins (US Patent No. 5,290,701) discloses a microbial detection and process with **morphological variation** and identification criteria analysis (see Abstract, last line").

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY CHAN whose telephone number is (571)272-1956. The examiner can normally be reached on 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melissa J Koval can be reached on 571-272-2121. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EC  
6/18/11

/MELISSA J KOVAL/

Supervisory Patent Examiner, Art Unit 2858